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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,184	11/28/2001	Luis Z. Avila	5181	3918

24536 7590 01/11/2005

GENZYME CORPORATION  
LEGAL DEPARTMENT  
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FRAMINGHAM, MA 01701-9322

EXAMINER

AZPURU, CARLOS A

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/996,184

**Applicant(s)**

AVILA ET AL.

**Examiner**

Carlos A. Azpuru

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9 and 11-23 is/are rejected.
- 7) ☒ Claim(s) 8 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt is acknowledged of the request for continued examination filed 10/01/2004, and the papers drawn to the power of attorney filed 10/22/2005.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9, 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney et al (US Patent No. 6,083,524).

Sawhney et al disclose water-soluble, biocompatible and biodegradable macromers, wherein the water-soluble region includes polymeric blocks prepared from PEG, polyethylene oxide, polyvinylpyrrolidone, carboxymethyl cellulose, hyaluronic acid dextran and several other water soluble polymers (see Abstract; col. 5, lines 40-53).

The PEG backbone can be reacted with trimethylene carbonate (TMC) (see col. 3, line 1 to col. 6, line 62). After which the terminal hydroxy groups of the TMC-PEG polymer can be reacted with acryloyl chloride to end-cap the polymer with acrylate end-groups, to provide a macromer with reactive functionality, and subsequent reaction of the end groups in an aqueous environment which results in a bioabsorbable gel (see col. 9, lines 40-60). Sawhney et al provides compositions comprising PEG macromers having

Art Unit: 1615

crosslinkable groups, biodegradable regions and reactive groups (see col. 6, lines). The citations above show the PEG macromers and reactive groups are discussed at col 9, lines 54-56 in particular. While Sawhney et al do not use the terminology of PIP polymers, these same polymers (are discussed for incorporation into the water-soluble regions of the macromer along with PEG. Those of ordinary skill would have therefore been able to modify the content of such "PIP" polymers per their disclosure in the macromer composition of Sawhney et al in order to meet the viscosity characteristics needed for their end use. This selection and modification is viewed as a perfecting step in what is already an art recognized composition. This is particularly relevant in view of Sawhney et al and their disclosure of the same art recognized use of the claimed compositions (ie tissue sealants, adhesion prevention, drug delivery) at cols. 11-13. As such, those of ordinary skill would have expected similar therapeutic results from the use of the instant macromers given the disclosure of Sawhney et al. The instant composition and method would have been obvious given the disclosure of Sawhney et al which discloses macromers within the scope of those claimed herein, and for the same art recognized therapeutic purposes.

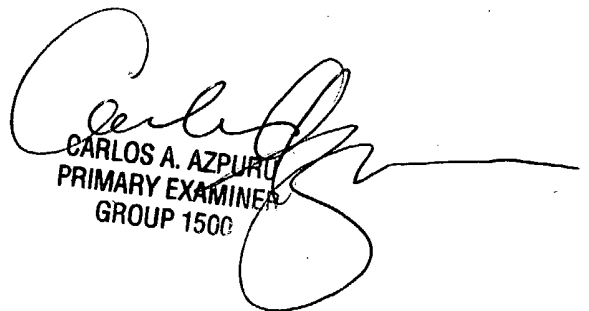
Claims 8 and 10 are objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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